DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2014

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.,
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K141083
Trade/Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 24, 2014
Received: July 25, 2014

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

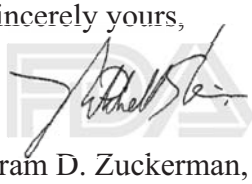
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141083

Device Name

Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X

Indications for Use *(Describe)*

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K141083 .

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: April 25, 2014

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Mircolife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

a. Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C, K092456, Microlife Intellectual Property GmbH.

b. Microlife Wrist Watch Blood Pressure Monitor, Model BP3MO1-3P, K120430,

Microlife Intellectual Property GmbH

4. Device Description:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses a capacitor pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the “oscillometric method”.

The device has Irregular Heartbeat Detection (IHD) function. It detects the appearance of irregular heartbeat during measurement and the irregular heart beat symbol "  " is displayed on the LCD screen if any irregular heart beat signal has been detected. In addition, the device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

5. Intended Use:

The Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

The subject BP3NU1-4X and the predicate device model BP3BS1-3C, use the same oscillometric method with the same fundamental scientific technology to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated automatically by pump and the pressures are transferred via tubing to a sensor in these two units.

They differ by the traffic light function, Blood Pressure Analyzer Software version, and MAM function. The traffic light function and MAM function are added to the subject device. But those differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology .Therefore repeated clinical test in accordance with the standard ANSI/AAMI SP10 is not necessary, please refer to "Clinical Declaration of Identity" in EXHIBIT #9a.

The subject BP3NU1-4X and the predicate BP3MO1-3P both has traffic light function. And the traffic light function has no impact on the clinical accuracy in terms of blood pressure detection.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

The subject device Model BP3NU1-4X is from the technical point of view, identical to the predicate blood pressure monitor. Moreover, the measurement algorithm and its program codes of BP3BS1-3C remain unchanged. The fundamental scientific technology of the modified BP3BS1-3C device is the same as the predicate device BP3NU1-4X. Therefore the performance of the BP3NU1-4X in terms of blood pressure measurement would be identical with performance of the predicate device BP3BS1-3C. Repeat clinical testing in accordance with the standard ANSI/AAMI SP10 for the subject device BP3NU1-4X is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

10. Conclusions:

We have demonstrated that there are no significant differences between the Microlife Wrist Watch Blood Pressure Monitor, Model BP3NU1-4X and the predicate devices, Model BP3BS1-3C and Model BP3MO1-3P, in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft “Reviewer Guidance for Premarket Notification Submissions”, and the ANSI/AAMI Voluntary Standard, SP10: 2008，AAMI / ANSI / IEC 80601-2-30:2009.